

**510(k) Summary**  
**Lucent® Magnum+**

510(k) Number 15081711 (pg 1 of 2)

**Manufacturer Identification**

**Submitted by:**

Spinal Elements, Inc.  
2744 Loker Ave. W., Suite 100  
Carlsbad, CA 92010  
760-607-0121

SEP 11 2008

**Contact Information:**

Kerri DiMartino  
Regulatory Affairs Specialist  
Spinal Elements, Inc.  
2744 Loker Ave. W., Suite 100  
Carlsbad, CA 92010  
760-607-1816  
kdimartino@spinalelements.com

**Date Prepared:**

September 3, 2008

**Device Identification**

**Proprietary Name**

Lucent® Magnum+

**Common Name**

Vertebral Body Replacement;  
Intervertebral Body Fusion Device

**Device Classification**

21 CFR 888.3060 (spinal intervertebral body  
fixation orthosis);  
21 CFR 888.3080 (orthosis, spinal intervertebral  
fusion)

**Proposed Regulatory Class**

Class II

**Device Product Code**

MQP; MAX

**Device Description**

Spinal Elements' Lucent Magnum+ device is composed of a main device body and fixation screws. The main device body is generally oval-shaped with various holes throughout its geometry. The superior and inferior surfaces of the device have engagement members to prevent migration once surgically positioned. The main implant body has holes through it that allow for the passage of bone screws that affix to bone to help prevent migration.

Devices are available in a multitude of sizes. Device bodies are made from either titanium alloy (Ti-6Al-4V), conforming to ASTM F 136 or ISO 5832-3, or polyetheretherketone (PEEK-Optima®), conforming to ASTM F 2026. Screws are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F 136 or ISO 5832-3. All implants are intended for single use only and should not be reused under any

circumstances. Components from this system should not be used in conjunction with components from other systems.

***Intended Use of the Device******When used as a vertebral body replacement:***

When used as a vertebral body replacement, the device is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

***When used as an intervertebral body fusion device:***

When used as an intervertebral body fusion device, the device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). This device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

***Substantial Equivalence***

The Lucent Magnum+ device was shown to be substantially equivalent in indications for use, general design features, function, and materials to the following predicates: Lucent® by Spinal Elements (K071724), Lucent® Magnum by Spinal Elements (K073348), and STALIF TT™ by Surgicraft (K073109).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Spinal Elements, Incorporated  
% Ms. Kerri DiMartino  
Regulatory Affairs Specialist  
2744 Loker Avenue West, Suite 100  
Carlsbad, California 92010

SEP 12 2011

Re: K081711  
Trade/Device Name: Lucent® Magnum+  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD, MQP  
Dated: June 13, 2008  
Received: June 17, 2008

Dear Ms. DiMartino:

This letter corrects our substantially equivalent letter of September 11, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with the first name "Mark" being the most prominent.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K081711

Device Name: Lucent® Magnum+

### Indications for Use:

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When used as an intervertebral body fusion device, the device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

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Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Page 1 of 1  
Division of General, Restorative,  
and Neurological Devices

K081711  
510(k) Number \_\_\_\_\_